IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE, OR IN THE ALTERNATIVE, TO LIMIT THE OPINIONS AND TESTIMONY OF ELIZABETH MUELLER, M.D.

Dr. Mueller is an internationally recognized pelvic-floor surgeon who is board certified in Obstetrics and Gynecology, as well as Female Pelvic Medicine & Reconstructive Surgery. She is a tenured Professor of Urology and Obstetrics and Gynecology, and the Fellowship Director of Female Pelvic Medicine & Reconstructive Surgery at Loyola University Chicago Stritch School of Medicine and Loyola University Health System. In addition to her medical background and experience, she also has bachelor's and master's degrees in mechanical engineering, with certification in biomedical engineering, and worked in the mechanical-engineering field for a number of years before attending medical school. She is an active researcher in the field of pelvic medicine, has performed over 1,000 sling procedures using various TVT mesh devices, and has held various leadership positions in pelvic medicine-related professional organizations.

Dr. Mueller is therefore well qualified to offer opinion testimony, which is supported not only by her substantial clinical experience and teaching background, but also by high-quality scientific evidence. Her opinions are thus based on "good grounds" and will assist the trier of

fact to understand the evidence and determine facts in issue—namely, whether the TVT[1] is defective and whether Plaintiffs can meet their burden of establishing general and specific causation.

As more fully explained below, Defendants Ethicon, Inc., Ethicon, LLC, and Johnson and Johnson (Ethicon) respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Mueller's testimony.

ARGUMENTS AND AUTHORITIES

I. Dr. Mueller is qualified to testify about risks that are within the common knowledge of physicians and her opinions are reliable.

Plaintiffs argue that Dr. Mueller "rescinded" her warnings opinions and is otherwise unqualified to offer them because she never drafted an IFU or provided any input to a medical device company as to what should be included in an IFU. Pls.' Mem. (Dkt. 3612) at 2-3, 5. They alternatively argue that her warnings opinions are not reliable because Dr. Mueller did not "rely on" the IFU in forming her opinions. *Id*. at 2-4. Plaintiffs are mistaken and misunderstand Dr. Mueller's opinions.

A. Dr. Mueller is an experienced pelvic-floor surgeon who is qualified to give opinions about risks commonly known to pelvic-floor surgeons.

Dr. Mueller opines that the risks Plaintiffs' experts claim should be included in the IFU "are commonly known." Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 6, 24. In her opinion, "elemental risks," such as pain and dyspareunia, are risks "that can occur with any procedure," "are taught in residencies and fellowships, widely published in the peer-reviewed medical literature and textbooks, discussed at conferences, and learned throughout training and clinical experience." *Id*. at 6. This opinion is grounded in the scientific method, the law, within

[1] Although Dr. Mueller offers opinions on the TVT and TVT-O mesh products, the only plaintiff listed on Exhibit A to Plaintiffs' motion is Plaintiff Connie Thate, who was implanted with TVT.

her expertise, and consistent with the Court's Wave 1 rulings. Indeed, this Court has expressed "no opinion" about "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016).

And Dr. Mueller is well-qualified to offer opinions about risks are "commonly known" to pelvic-floor surgeons. Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 6, 24. As a tenured Professor of Urology and Obstetrics and Gynecology and Fellowship Director of the Female Pelvic Medicine and Reconstructive Surgery at Loyola University Chicago Stritch School of Medicine and Loyola University Health System, she is very knowledgeable about the required training curriculum for residents and fellows in pelvic-floor medicine because she is involved in it and directs it. *Id*. at 2. Moreover, as an experienced clinician and internationally recognized leader in Female Pelvic Medicine and Reconstructive Surgery and Urogynecology, she is on the cutting edge of the medical and scientific literature in her field and the latest developments that affect her practice. *Id*. at 1-4. Indeed, she has performed over 1,000 sling procedures using various TVT mesh devices over the course of her career and has published over 75 peer-reviewed articles in scientific research publications, many of which involve the treatment of urinary incontinence. *Id*. at 3, 6.

Consistent with this background, Dr. Mueller is well aware of what risks are within the common knowledge of pelvic-floor surgeons because not only is she an experienced pelvic-floor specialist, but she also teaches residents and fellows in this area of medicine. *Id*. at 2. In her opinion, pelvic surgeons are educated and trained on the multitude of potential risks of pelvic-floor surgery. *Id*. at 6, 24. In her opinion, although "[e]rosions can occur with any material used

in incontinence procedures," erosion of synthetic mesh is "commonly described as the only unique risk of midurethral slings." *Id.* at 8-9.

As an experienced pelvic-floor surgeon, she need not be familiar with FDA rules or regulations to give this testimony. *See United States v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (allowing FDA to offer evidence by affidavits of two medical experts as to what information is within common knowledge of physicians in a misbranding case); *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *6-7, 15 (S.D.W. Va. Apr. 24, 2015) (discounting Dr. Galloway's unfamiliarity with FDA regulations and requirements for warnings); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-04, 719 (S.D.W. Va. 2014) (finding Drs. Rosenzweig and Blaivas adequately experienced physicians to testify about risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *13-14 (S.D.W. Va. May 19, 2016) (finding Dr. Shull qualified to testify "on the completeness and accuracy of the [mesh product's] warnings from a clinical perspective" because his testimony did not touch on regulatory issues). Indeed, a physician is qualified to make a comparison between "the risks [the physician] perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id*. This principle is consistent with the rulings this Court recently issued for Wave 1 cases—namely, that a urogynecologist is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 (S.D.W. Va. Aug. 31, 2016).

Moreover, her opinions on this issue are consistent with the legal principle that Ethicon, like other medical device manufacturers, has no duty to warn pelvic-floor surgeons of risks

commonly known to attend pelvic-floor surgery. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (instructing that the duty to warn is of dangers "not well known to the medical community"); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339, at *7 (S.D.W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community.'"). As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings, and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

Based on this support, Dr. Mueller is qualified to offer the opinion that Plaintiffs really challenge—*i.e.*, that the risks Plaintiffs' experts claim should be included in the IFU are "commonly known" to pelvic-floor surgeons because they are part of a pelvic-floor surgeon's clinical training and professional development, and are widely published in peer-reviewed medical literature and textbooks, and discussed at conferences. Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 5-6, 24. As a tenured Professor of Obstetrics and Gynecology and Urology, Fellowship Director of Female Pelvic Medicine and Reconstructive Surgery, and a seasoned researcher and an experienced practicing surgeon who went through years of medical education and training, Dr. Mueller is eminently qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic-floor surgeries.

It is of no consequence then that Dr. Mueller has never drafted an IFU, or offered input to a medical device manufacturer about information to be included in an IFU, because she is not offering an opinion that the TVT IFU is adequate as Plaintiffs claim. Indeed, Ethicon is mindful of the Court's Wave 1 ruling that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU should or should not include." *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4557036, at *3. Dr. Mueller will not be offering opinions about what should or should not be included in an IFU. Ethicon respectfully submits, however, that risks that are within the common knowledge of physicians are risks that would not, as a matter of logic, be included in an IFU. This logical result, however, does not mean that an expert's common-knowledge testimony should be excluded under the Court's exclusionary "additional expertise" directive. Instead, the Court's directive goes to the lack of expertise in regulatory requirements and compliance, not whether a particular risk is within the common knowledge of physicians. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015) (distinguishing between an expert's expertise "in the requirements for product labeling" and the expert's qualifications as a practicing physician to testify about risks provided in the text of the product's labeling).

In accordance with this distinction and the Court's limitations, Dr. Mueller will not testify about the regulatory requirements for product labeling for the IFUs at issue here or what the IFU should or should not include. But she is qualified by education, training, and experience to give opinions about what risks are within the common knowledge of surgeons who perform pelvic-floor surgery. Any disagreement Plaintiffs may have with Dr. Mueller's opinions on this issue goes to weight, not admissibility.

B. Her warnings opinions are reliable.

In reaching her opinions about what is commonly known in the field of pelvic medicine, Dr. Mueller relied not only on her education, training, and professional experience, but also on her clinical research and teaching, her review of the medical and scientific literature, as well as her experience as a reviewer for leading medical journals in her field. Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 8. And she supports her opinions with numerous references to scientific articles and studies, which she discusses in detail in her report. *Id*. at 8-24. These are all well established and accepted methodologies. *See, e.g.*, *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014) (explaining that a physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*"). Her resulting opinions are therefore reliably reached.

II. Dr. Mueller—an experienced pelvic-floor surgeon—need not be a specialist in materials science to opine about mesh properties and her mesh-properties opinions are reliable.

A. She is qualified to offer mesh-properties opinions.

Plaintiffs claim that Dr. Mueller's opinions about mesh properties—*i.e.*, that polypropylene does not degrade and that the various properties of mesh, including porosity, weight, density, and whether cut mechanically or by laser, have not been shown to be clinically significant—are "design" opinions that she is not qualified to offer. To Plaintiffs, even though Dr. Mueller holds a master's degree in mechanical engineering, she is not a *materials* engineer, has never designed a mesh product or any product, has never examined explanted mesh under an electron microscope, and has "no knowledge of the design process." Pls.' Mem. (Dkt. 3612) at 6-7, 9. Plaintiffs' argument fails for two reasons.

1. A degree in materials science is not required.

This Court has repeatedly instructed that an expert need not be a materials engineer or designed a mesh product to offer opinions about various mesh properties. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493535, at *3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Bales's is unqualified to offer opinions about whether mesh degrades because he is not an engineer); *see also In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582210, at *4 (S.D.W. Va. Sept. 1, 2016) (rejecting plaintiffs' argument that Dr. Horbach is not qualified to offer opinions about mesh properties because she never designed a mesh product). Instead, an expert with extensive clinical experience in urogynecology who has reviewed the relevant literature—as Dr. Mueller did here—is qualified to give opinions about mesh properties. *Id.*

Nor does Dr. Mueller need to be an expert in materials engineering to give opinions about mechanical- versus laser-cut mesh, as Plaintiffs claim. *See* Pls.' Mem. (Dkt. 3612) at 9. Like Dr. Kenton in *In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation*, MDL No. 2327, 2016 WL 4945099, at *2-3 (S.D.W. Va. Aug. 31, 2016), Dr. Mueller has "significant clinical experience implanting both mechanically cut and laser cut midurethral slings" (Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 6), which makes her qualified to offer opinions about the clinical differences between those two cuts of mesh even though she is not a materials engineer. *In re: Ethicon Inc.*, 2016 WL 4945099, at *2-3 (rejecting plaintiffs' argument that Dr. Kenton is unqualified to offer opinions about the clinical differences between because she is not an engineer).

The same holds true for Dr. Mueller's opinions about porosity and weight, or any other mesh property. Dr. Mueller need not be a materials engineer to give these opinions or have examined explanted mesh under an electron microscope. *See In re: Ethicon, Inc. Pelvic Repair*

Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4944702, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that Dr. Schwartz is unqualified to offer opinions about pore size, among other mesh properties opinions, because he is not an engineer and never analyzed explanted mesh under a microscope). Instead, an expert with extensive clinical experience as Dr. Mueller has here, qualifies her to opine about the mesh's reaction to and effect on the human body. *Id.*; *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that Dr. Serels is not qualified to offer various mesh properties opinions because he is not an engineer or pathologist); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493364, at *2-3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Toglia is not qualified to offer opinions about polypropylene safety and mesh weight because he is not an engineer).

It makes no difference then that Dr. Mueller is not a materials engineer or that she has never designed a mesh product. Her extensive clinical experience and review of the literature qualifies her to opine about the TVT mesh's clinical effect on the human body as well as the safety and efficacy of mesh products.

2. Dr. Mueller is not offering opinions about the process of designing a product.

Plaintiffs' design argument fails for a second reason as well. Although Plaintiffs criticize Dr. Mueller because she "has no knowledge of the design process" (Pls.' Mem. (Dkt. 3612) at 7), she is not offering opinions about the *process* of designing a product that would require expertise in materials engineering or product design. On the contrary, she is opining about the clinical effects of various mesh properties on the human body based on her extensive clinical experience with the TVT mesh product. Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 17-24.

As this Court has said repeatedly, an expert's "mere utterance" of the word "design" does not transform the expert's opinion into a design opinion. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493585, at *3 (S.D.W. Va. Aug. 25, 2016). It is only when the expert offers opinions "about the process of designing a product" that the expert can be considered to have offered a design opinion. *Id.* (rejecting plaintiffs' argument to exclude Dr. Anhalt's "design" opinion because he did not offer any opinions about the process of designing a product); *see also, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4547053, *3 (S.D.W. Va. Aug. 31, 2016) (same as to Dr. Grier); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4958312, at *3-4 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Carbone), among others.

Like Drs. Anhalt, Grier, Elser, and Carbone in these cases, Dr. Mueller offers no opinions about the *process* of designing a product. Plaintiffs' criticisms about her lack of experience in product design and the product design process should be rejected.

B. Dr. Mueller's mesh-properties opinions are reliable.

As discussed, Dr. Mueller has extensive clinical, surgical, research, and teaching experience. *See supra* Section I.A. She has also conducted a thorough review and analysis of the peer-reviewed scientific literature, which she discusses extensively in her reports. Ex. B to Pls.' Mot. (Dkt. 3610-2), Mueller Report at 8-24. This Court has found that this experience and the thorough analytical review of the scientific literature Dr. Mueller has performed, are reliable methodologies for reaching expert opinions. *Eghnayem*, 57 F. Supp. 3d at 714 (finding a physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*"); *see also Tyree v. Boston Scientific Corp.*, 54 F.

Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that board-certified urologist's opinions about mesh safety and efficacy were reliable where they were based on his clinical experience).

Plaintiffs claim that Dr. Mueller "ignored a large body of evidence" and had "no sense of what the internal workings have been of Ethicon." Pls.' Mem. (Dkt. 3612) at 9. Yet, Plaintiffs have not identified any evidence let alone a "large body" of it that Dr. Mueller failed to consider in forming her opinions. *Id*.

Nor is Dr. Mueller's unfamiliarity with Ethicon's internal documents or its internal workings make her mesh-properties opinions unreliable. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4944334, at *3 (S.D.W. Va. Sept. 1, 2016) (rejecting plaintiffs' argument that Dr. Irwin's mesh-properties opinion is unreliable because she did not review internal company documents; "I do not find Dr. Irwin's unfamiliarity with Ethicon's internal documents . . . to undermine the reliability of her opinions"); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4549102, at *4 (S.D.W. Va. Aug. 31, 2016) (rejecting plaintiffs' argument that Dr. Bergmann's mesh-properties opinion is unreliable because it conflicted with an Ethicon internal document; "I do not find that Dr. Bergmann's unfamiliarity with Ethicon's internal document on particle loss has any bearing on her reporting of her personal experience with particle loss"). As these decisions make clear, Dr. Mueller need not have studied or relied upon Ethicon's internal documents to give an opinion on mesh properties based on her prolific research, vast clinical experience, and extensive review of the medical literature.

Plaintiff's reliance on *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 12685965 (S.D.W. Va. Nov. 20, 2014) as establishing an "objective standard[]" to reach an "objective opinion[]" (Pls.' Mem. (Dkt. 3612) at 10) is not a correct statement of the reliability analysis

required under *Daubert* and otherwise misses the mark. The excerpt Plaintiffs claim support their "objective standard" argument has nothing to do with the analysis for reliability. Instead, the Court was analyzing the warnings opinions offered by both Drs. Elser and Pramudji on qualifications grounds. *Bellew*, 2014 WL 12685965, at *17-18. But even more importantly, *Daubert* does not establish an objective standard that expert witnesses must satisfy for their opinions to be reliable under Rule 702. On the contrary, to pass *Daubert* scrutiny, an expert must employ reliable methodologies that follow the scientific method to reach an opinion that is supported by good grounds. Plaintiffs' attempt to interject a standard not supported by *Daubert* and its progeny should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' Motion to Preclude, or in the Alternative, to Limit the Opinions and Testimony of Elizabeth Mueller, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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